

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION)	MDL NO. 1203
)		
)		
THIS DOCUMENT RELATES TO:)	
)		
SHEILA BROWN, et al.)	
)		CIVIL ACTION NO. 99-20593
v.)	
)		
AMERICAN HOME PRODUCTS CORPORATION)	2:16 MD 1203
)		

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8563

Bartle, C.J.

November 16, 2010

Linda M. Pflug ("Ms. Pflug" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Richard G. Pflug, Ms. Pflug's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the
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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In September, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Robert N. Notske, M.D., F.A.C.C., F.A.C.P. Dr. Notske is no stranger to this litigation. According to the Trust, he has signed in excess of 45 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated June 18, 2003, Dr. Notske attested in Part II of Ms. Pflug's Green Form that she suffered from moderate mitral regurgitation, moderate or greater mitral

3. (...continued)

presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

regurgitation confirmed by echocardiogram prior to the use of Pondimin and/or Redux,⁴ and an abnormal left atrial dimension.⁵ Based on such findings, claimant would be entitled to Matrix B-1, Level II benefits in the amount of \$96,609.⁶

In the report of claimant's June 18, 2003 echocardiogram, the reviewing cardiologist, Donald B. Canaday, M.D., F.A.C.C., stated that claimant had "[m]oderate mitral regurgitation with RJA/LAA~39%." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In February, 2004, the Trust forwarded the claim for review by David B. Lieb, M.D., one of its auditing cardiologists. In audit, Dr. Lieb concluded that there was no reasonable medical

4. The presence of moderate or greater mitral regurgitation confirmed by echocardiogram prior to the use of Pondimin and/or Redux requires the payment of reduced benefits for a mitral valve claim. See Settlement Agreement § IV.B.2.d.(2)(c)iii)c).

5. Dr. Notske also attested that claimant suffered from New York Heart Association Functional Class II symptoms. This condition, however, is not at issue in this claim.

6. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

basis for Dr. Notske's finding that claimant had moderate mitral regurgitation because her June 18, 2003 echocardiogram demonstrated only mild mitral regurgitation. In support of this conclusion, Dr. Lieb explained that:

The study I reviewed on CDROM shows a cine loop of the apical 4 chamber view with no more than mild mitral insufficiency by visual estimation. There is a single frame recorded and measured at 17:20:18, many minutes later, without ECG to confirm either the point in the cardiac cycle or exclude a PVC, which we are told are frequent. Though this measurement would be consistent with moderate insufficiency, it cannot be confirmed nor does it appear representative of any other cycles seen.

Based on Dr. Lieb's finding that claimant had mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Pflug's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁷ In contest, claimant submitted a declaration from her attesting physician, Dr. Notske, wherein he disagreed with the auditing cardiologist's assessment that the single frame relied upon for the diagnosis of moderate mitral regurgitation was unreliable.⁸ Dr. Notske further stated that

7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Pflug's claim.

8. Dr. Notske's declaration mistakenly refers to the
(continued...)

claimant's previous echocardiograms demonstrated moderate mitral regurgitation and, therefore, the single frame was not an "anomaly," but rather representative of claimant's true level of regurgitation. In addition, claimant submitted a letter from Dr. Canaday, wherein he reaffirmed his finding of moderate mitral regurgitation.⁹ Finally, claimant included a letter from the Trust reporting the results of an echocardiogram performed in the Trust's Screening Program¹⁰ that demonstrated moderate mitral regurgitation.

The Trust then issued a final post-audit determination, again denying Ms. Pflug's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Pflug's claim should be paid. On May 20, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5238 (May 20, 2005).

8. (...continued)
echocardiogram of a claimant not related to this show cause proceeding.

9. Dr. Canaday also stated that the results of an April 5, 2004 echocardiogram confirm that claimant had moderate mitral regurgitation.

10. See Settlement Agreement § IV.A.1.a. (Screening Program established under the Settlement Agreement).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on September 15, 2005, and claimant submitted a sur-reply on October 4, 2005. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor¹¹ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, James F. Burke, M.D., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue,

11. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Pflug reasserts the arguments made in contest; namely, that the auditing cardiologist erred in his analysis of Ms. Pflug's claim. Claimant again relies on the declaration from Dr. Notske and the letter from Dr. Canaday. In addition, Ms. Pflug contends that there is a reasonable medical basis for her claim because Dr. Notske and Dr. Canaday were "precise" while Dr. Lieb only provided "visual estimation." Claimant also submits the reports of two echocardiograms performed in 1994 and 2002, which she argues provide a reasonable medical basis for Dr. Notske's Green Form representation. Finally, claimant argues that multiple loops demonstrating moderate mitral regurgitation are not required for the attesting physician to find a reasonable medical basis that claimant had moderate mitral regurgitation.

In response, the Trust asserts that claimant has failed to prove that there is a reasonable medical basis to support her attesting physician's finding of moderate mitral regurgitation. The Trust contends that Dr. Notske failed to review multiple loops and frames and set an inappropriately low Nyquist limit. The Trust also asserts that, while the auditing cardiologist did

not provide specific measurements as to claimant's level of regurgitation, he did visually assess claimant's level of regurgitation, which is "well accepted in the world of cardiology."

In her sur-reply, claimant submits a supplemental declaration from Dr. Notske. In his supplemental declaration, Dr. Notske stated that in evaluating claimant's level of mitral regurgitation, he "reviewed multiple loops and frames; observed the regurgitant jet through a portion of systole ...; took into account the Nyquist setting ...; and ... did not characterize 'artifacts,' 'phantom jets,' 'backflow' or other low velocity flow as mitral regurgitation" Dr. Notske also submitted that he complied with the guidelines in Feigenbaum and Weyman.

The Technical Advisor, Dr. Burke, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Burke found, in relevant part, that:

In my assessment of [claimant's June 18, 2003] echocardiogram, I found the study was a technically difficult study to interpret. I believe that there were at least two things done in the performance of this echocardiographic study that would maximize a regurgitant jet of mitral regurgitation, potentially at the expense of technically limiting the overall study. These would include:

1. Excessive and inappropriate use of gain for the color flow Doppler.

2. The use of a low Nyquist limit of 42 for the color flow Doppler in the apical four chamber view for the recording of mitral regurgitation.

* * *

In the June 18, 2003 study, no color flow Doppler assessment for mitral regurgitation is presented in the parasternal long axis or the apical two chamber views.

In the apical long axis view (clip 16), I was not able to identify any definite evidence of mitral regurgitation with the technical limitations listed above. Similarly, in the subcostal view with color flow Doppler (clip 31), I could identify no definite evidence of mitral regurgitation.

With regard to the apical four chamber view, in clip 17, some degree of mitral regurgitation was noted. I would describe this mitral regurgitation as trace to mild. Only one single frame was technically adequate enough for me to attempt to calculate a RJA/LAA ratio. Using the frame with the maximal regurgitation, I calculated this ratio at 11%, in the range for mild mitral regurgitation. Clip 19 is also recorded in the apical four chamber view. There appears to be at least trace mitral regurgitation but the color flow image is cut off to not permit further assessment of the degree of mitral regurgitation. Clip 27 is also recorded in the apical four chamber view. This is a frozen image that shows some blue color in the left atrium. I am uncertain as to what this represents. It does not appear to be mitral regurgitation. I suspect this represents back flow. This image certainly does not appear in any of the real time images I was able to review. The clip 36 is a color flow Doppler freeze frame in the apical four chamber view. The time on this is labeled 17:20:18 and describes the single image reviewed by David Lieb, M.D. I concur with the assessment of David Lieb, M.D. This single shot is not representative of the real time images I was able to review on this June 18, 2003 echocardiographic

study. I am uncertain that the color flow image traced in the left atrium represents mitral regurgitation.

My overall assessment was that [claimant's] mitral regurgitation was trace to mild in this study.

In response to the Technical Advisor Report, claimant contends that the Technical Advisor "cites no violation of any protocol established by Feigenbaum (1994) or Weyman (1994)," and that these protocols do not require a regurgitant jet be representative. According to claimant, there is a reasonable medical basis for Dr. Notske's Green Form representation because both the auditing cardiologist and Technical Advisor agree that at least one frame in claimant's echocardiogram demonstrated moderate mitral regurgitation. Claimant also asserts that to compensate for her body size, Dr. Canaday had to adjust the Nyquist level and gain settings to get the best images. In addition, Ms. Pflug submits that because there is no claim by the Technical Advisor that the Nyquist or gain settings were inappropriate for claimant's body type, there is no basis for Dr. Burke's finding that manipulation of these settings diminishes the legitimacy of the findings in the echocardiogram report at issue. Finally, Ms. Pflug argues that the reports for her echocardiograms performed in 1994 and 2002 provide a reasonable medical basis for Dr. Notske's finding of moderate mitral regurgitation.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, claimant does not

adequately challenge the findings of the Technical Advisor. Specifically, Dr. Burke determined that, based on the only frame in the apical four chamber view that was technically adequate, "the maximal regurgitation [was calculated at a ratio of] 11%, in the range for mild mitral regurgitation." Claimant never identified any particular error in Dr. Burke's assessment. Mere disagreement with the Technical Advisor is insufficient to meet a claimant's burden of proof. On this basis alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.

We also disagree with claimant that the opinions of Dr. Notske and Dr. Canaday provide a reasonable medical basis for Dr. Notske's finding of moderate mitral regurgitation. As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002). Here, Dr. Burke determined that the echocardiogram settings were over-manipulated (i.e., excessive and inappropriate use of gain for

the color flow Doppler) and that the echocardiogram had an inappropriately low Nyquist limit. In addition, Dr. Burke concluded that several still frames on the echocardiogram tape either did not allow for assessment, did not appear in the real time images, represented backflow, or were not representative of the regurgitation seen in real time.¹² Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation that claimant suffered from moderate mitral regurgitation.¹³

In addition, we reject claimant's argument that Dr. Burke did not apply the appropriate standard in evaluating Ms. Pflug's echocardiogram. Specifically, Dr. Burke concluded that claimant's echocardiogram demonstrated a maximum RJA/LAA ratio of 11%. Although claimant objects to Dr. Burke's use of "representative" frames to evaluate claimant's level of mitral regurgitation, we have held that "[f]or a reasonable medical basis to exist, a claimant must establish that the findings of the requisite level of mitral regurgitation are representative of the level of regurgitation throughout the echocardiogram."

PTO No. 6997 at 11 (Feb. 26, 2007). "To conclude otherwise would

12. In any event, we previously have stated that still frames alone are not sufficient to determine a claimant's level of mitral regurgitation. See, e.g., PTO No. 6897 at 7 (Jan. 26, 2007) (further citation omitted).

13. Moreover, claimant's 1994 and 2002 echocardiogram reports do not provide a reasonable medical basis for Dr. Notske's representation that claimant had moderate mitral regurgitation based on her June 18, 2003 echocardiogram.

allow claimants who do not have moderate or greater mitral regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement." Id.

Moreover, claimant's assertion that she is entitled to Matrix Benefits because the attesting physician's findings are supported by the echocardiogram conducted in the Screening Program for Fund A Benefits under the Settlement Agreement is misplaced. See Settlement Agreement § IV.A. The Settlement Agreement clearly provides that the sole benefit that a class member is entitled to receive for a favorable echocardiogram under the Screening Program is a limited amount of medical services or a limited cash payment:

All Diet Drug Recipients in Subclass 2(b) and those Diet Drug Recipients in Subclass 1(b) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, will be entitled to receive, at the Class Member's election, either (i) valve-related medical services up to \$10,000 in value to be provided by the Trust; or (ii) \$6,000 in cash.

Id. § IV.A.1.c. Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

Indeed, this conclusion is confirmed by the Settlement Agreement provisions concerning claimants eligible for Matrix Benefits. Specifically, claimants with a diagnosis of FDA Positive or mild mitral regurgitation merely become eligible to seek Matrix Benefits. See id. § IV.B.1. Further, adopting

claimant's position would be inconsistent with Section VI.E. of the Settlement Agreement, which governs the audit of claims for Matrix Benefits, as well as this court's decision in PTO No. 2662 (Nov. 26, 2002), which mandated a 100% audit requirement for all claims for Matrix Benefits. See PTO No. 2662 at 13. As nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram for purposes of Fund A Benefits results in an immediate entitlement to Matrix Benefits, we decline claimant's request to interpret the Settlement Agreement in this fashion.

Finally, we also disagree with claimant's argument that the auditing cardiologist inappropriately relied on "visual estimation." Although the Settlement Agreement specifies the percentage of regurgitation needed to qualify as having moderate mitral regurgitation, it does not specify that actual measurements must be made on an echocardiogram. As we explained in PTO No. 2640, "'[e]yeballing' the regurgitant jet to assess severity is well accepted in the world of cardiology." PTO No. 2640 at 15. Claimant essentially requests that we write into the Settlement Agreement a requirement that actual measurements of mitral regurgitation be made to determine if a claimant qualifies for Matrix Benefits. There is no basis for such a revision, and claimant's argument is contrary to the "eyeballing"

standards we previously have evaluated and accepted in PTO No. 2640.¹⁴

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Pflug's claim for Matrix Benefits and the related derivative claim submitted by her spouse.

14. The Technical Advisor, although not required to, made a specific measurement of claimant's level of mitral regurgitation, which further establishes that she is not entitled to Matrix Benefits.